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Russia

Alexander Skoblo and Maria Volodina

Salans

Organisation and financing of health care

1 How is health care in your jurisdiction organised?

Health care is governed primarily by the Fundamental Legislation on Protection of the Health of Citizens dated 22 July 1993 and the Law on Medical Insurance of Citizen dated 28 June 1991.

The Russian health-care system comprises three elements:

- the state (ie, federal governmental) system, including, in particular, state hospitals and research institutions, pharmacies and drug stores. The state health-care system plays a central role and is the cornerstone of the organisation of health care and medical services in Russia;
- the municipal system, including, in particular, municipal medical organisations, pharmacies and chemists; and
- the private system, including, in particular, privately owned clinical institutions and chemists, private medical practitioners and private pharmacists. Private health-care institutions that are properly registered may offer inpatient and outpatient health-care services provided they comply with the licensing requirements. The laws regulating the activities of private health-care institutions are currently evolving.

Medical and pharmaceutical activities require licences. The procedure and terms for obtaining licences are provided in applicable law.

2 How is the health-care system financed in the outpatient and inpatient sectors?

Russian health care in both the outpatient and inpatient sectors is in practice financed by state or municipal budgets and mandatory contributions by legal entities and individual entrepreneurs into extra-budgetary funds, although the law does recognise the possibility of other funding sources such as charitable donations. These are used as the financial resources of state and municipal health-care systems, and the financial resources of the state mandatory medical insurance system.

The state programme guaranteeing medical care for Russian citizens establishes that the following services are provided free of charge using these resources:

- primary public health care (both outpatient and inpatient);
- ambulance services, including specialised medical care (eg, air ambulances); and
- high-technology and other specialised medical care for illnesses requiring special diagnostic methods.

In the event of illness, incapacitation, or in other cases, Russian citizens have the right to social medical care (such as free meals), as well as social care if sick, incapacitated and disabled, including payment of temporary incapacity benefits. Free-of-charge medical care for Russian citizens is provided by state and municipal health-care institutions in accordance with mandatory medical insurance programmes.

Russian citizens can seek additional medical and other services on the basis of voluntary medical insurance programmes and where paid for by organisations or individuals.

As stated in question 1, private medical establishments are financed primarily by fees charged to patients and investments from their founders.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertisement of medicinal products to the general public and health-care professionals?

The advertisement of medicinal products in Russia is governed by the following laws:

- Federal Law No. 61-FZ dated 12 April 2010 on the Circulation of Medicines;
- Federal Law No. 38-FZ dated 13 March 2006 on Advertising; and
- Federal Law No. 135-FZ dated 26 July 2006 on Protection of Competition (this law contains provisions on unfair advertising and competition).

The Law on Advertising provides special requirements for advertising pharmaceutical products, medical equipment, medical purpose items and medical services, including treatment methods. The law imposes a number of restrictions on such advertisements, particularly for advertising through the mass media.

The member companies of the Association of International Pharmaceutical Manufacturers (AIPM) have also drawn up and approved a Marketing Code of Practice, which is a list of requirements that AIPM members must meet in their marketing activities in Russia.

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

The requirements for advertising targeted at health-care professionals are less strict than those targeted at the general public. As long as exclusively carried out at venues for medical or pharmaceutical exhibitions, seminars, conferences and other such events, and in specialised publications for medical and pharmaceutical professionals, the following are permitted:

- advertising of medicines in dose form prescribed by doctors, treatment methods, medical purpose items and medical equipment that require special training to use;
- advertising of medicines containing restricted narcotic or psychotropic substances permitted for medical use; and
- advertising that would otherwise be prohibited because it:
 - contains references to specific cases in which a person was cured or his health improved by using the advertised product;
 - includes ‘thank you’ messages from individuals concerning the advertised product; or

- fails to include the warning described in greater detail in question 5 of side effects from the use of the medical product or treatment method, or a warning of the need to read the instructions or consult a specialist before use.

5 What are the main rules and principles applying to advertising aimed at the general public?

Advertisements aimed at the general public for pharmaceutical products, medical services and medical equipment, including treatment methods, must be accompanied by a warning of side effects and the need to read the instructions or consult a specialist (the duration of such warnings must be not less than three seconds for a radio advertisement; not less than five seconds and 7 per cent of the screen space for television, cinema and video advertising; and not less than 5 per cent of the size of the advertisement (or advertising space) for advertisements distributed by other means).

Pharmaceutical product advertisements aimed at the general public must not:

- be addressed to minors (ie, persons under 18);
- refer to successful cures or improvements in health due to use of the advertised product;
- contain 'thank you' messages from individuals relating to use of the advertised product;
- suggest benefits of the advertised product based on tests required for state registration of the product;
- contain assertions or assumptions that consumers suffer from some illness or form of ill health;
- suggest that healthy people need to use the advertised product;
- imply that it is not necessary to consult a doctor;
- guarantee the positive effects, safety, effectiveness and absence of side effects of the advertised product;
- present the advertised product as a biologically active supplement or food supplement, or any other non-pharmaceutical product;
- contain assertions that the natural origin of the advertised product guarantees its safety or effectiveness.

Advertising promotions involving giveaways of pharmaceutical products containing narcotic and psychotropic substances are prohibited.

6 What are the most common infringements committed by manufacturers with regard to the advertisement rules?

The most common infringements in the advertising of pharmaceutical products, medical equipment, medical purpose items and medical services, including treatment methods, relate to infringement of the requirements for side effect warnings, the need to read the instructions, or to consult a specialist.

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

Under applicable Russian law, all information on the properties and characteristics of medicines and medical equipment can be provided solely to the extent of the approved instructions for use of the advertised product. Therefore, all advertising and marketing materials for a pharmaceutical product must be consistent with the instructions for use.

At the same time, the law allows greater latitude to information on prescribed medicines that is provided solely to professionals, as in monographs, research articles, guidebooks, conference or roundtable reports, as well as in the instructions for use. The law is silent as to whether the issue of off-label use of medicines may be addressed in these or other sources.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals?

At present, relationships between health-care professionals and the pharmaceutical industry are not legislatively regulated.

However, draft laws on this issue are currently under consideration by government committees. In particular, draft amendments to the Fundamental Legislation on Protection of the Health of Citizens are currently under discussion. These draft amendments are 'intended to prevent the negative aspects of collaboration between health-care professionals and the pharmaceutical industry'.

The draft law proposes restrictions on pharmaceutical industry representatives and health-care professionals. Members of the medical community will be barred from:

- accepting gifts, cash bonuses, paid entertainment, vacations, or travel, as well as from participating in entertainment, that is paid for by organisations producing or distributing medicines;
- entering into written or oral agreements with companies concerning the prescription or recommendation of medicines to patients;
- receiving sample medicines from companies to give away to patients; and
- providing false or incomplete information on the number, type and name of medicines that may be substituted for a prescribed medicine.

Other legislative amendments are also currently being proposed in order to make health-care professionals and pharmaceutical company representatives administratively liable for a breach of the above requirements. Based on publicly available information, the maximum level of liability suggested is a two-year bar from practising medicine or pharmacy.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

The main rules and principles of cooperation between doctors and pharmaceutical companies are set out in the Doctors' Code of Ethics of the Russian Federation, adopted by the medical community in 1997 (the Code is complementary to law, rather than a substitute for it). The Code states that:

[A] doctor shall not accept incentives from manufacturers or distributors of pharmaceutical products for the prescription of their products. A doctor shall prescribe medicines strictly on the basis of medical factors and solely in the interests of the patient.

Regarding collaboration between the medical community and foreign pharmaceutical companies, the AIPM Marketing Code of Practice provides basic principles for such collaboration, providing, in particular, that such collaboration should:

- be intended to inform health-care professionals of pharmaceutical products, provide them with scientific and educational information, and support scientific research in medicine and medical education;
- not cause a conflict of interests, in particular, between professional obligations and economic interests; and
- must not involve pharmaceutical companies offering, promising, providing or giving health-care professionals any kind of remuneration for prescribing or recommending certain pharmaceutical products to patients, supporting professional training, (including sponsoring participation in conferences and other professional events, as well as issuing grants, stipends, and subsidies) and should not be made contingent on the amount of a pharmaceutical product prescribed or sold.

10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

Given that the relationship between health-care professionals and pharmaceutical companies is not governed by law, no statistics on infringements are available.

However, the Federal Antimonopoly Service (which is responsible for consumer protection generally) has stated one of the main infringements committed by pharmaceutical companies is improper marketing involving the creation of a material and psychological dependency between health-care professionals and pharmaceutical companies, as well as giving doctors a material interest in the prescription of a particular pharmaceutical product to the greatest possible number of patients.

11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

Patient organisations are relatively new to Russia and to date there is no legal or regulatory framework governing their relationship with the pharmaceutical industry.

The rights of individual patients vis-à-vis pharmaceutical companies is more developed. According to the Russian Declaration of Patients' Rights, adopted in May 2010:

[E]very person has the right to direct access to information on scientific research, the possibilities of pharmaceutical therapy, and technological innovation. This information may be provided by public or private sources, provided it meets criteria for accuracy, reliability, and transparency.

Rules are also set out in the AIPM Marketing Code of Practice, which states, in particular, that 'when a patient asks a pharmaceutical company for information, such requests must be satisfied'. However, this has been approved by international pharmaceutical companies doing business in Russia that are members of the AIPM.

12 Are manufacturers' infringements of competition law pursued by national authorities?

The Federal Antimonopoly Service of Russia supervises and oversees goods markets in accordance with Federal Law No. 135-FZ dated 26 July 2006 on the Protection of Competition. This law is intended to protect competition and create conditions for product markets in Russia to function effectively.

The Federal Antimonopoly Service performs the following main functions:

- state supervisory control of antimonopoly compliance;
- detection, termination and punishment of antimonopoly violations and monopolistic activities;
- state supervisory control of economic concentration (including control of the establishment and reorganisation of companies and approval of share transactions in specific cases), and of auctions and tenders in cases established by law.

In accordance with applicable competition law, the Federal Antimonopoly Service may, either on its own accord or on the basis of complaints by interested persons, initiate and consider antimonopoly violation cases by way of administrative proceedings.

13 Is follow-on private antitrust litigation against manufacturers possible?

In addition to their right to petition the Federal Antimonopoly Service as noted above, individuals can directly pursue administrative and court proceedings in order to protect their rights, including against manufacturers of medicines and pharmaceutical products.

Individuals can also have recourse to public non-commercial organisations (for example, the Russian Patients' Defence League) to defend their rights.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Advertisements for medical devices and advertising for medicinal products are governed by the same law – the Law on Advertising. As with pharmaceutical companies, the relations between manufacturers of medical devices and health-care professionals and patient organisations are not regulated by law.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

Federal Law No. 61-FZ dated 12 April 2010 on the Circulation of Medicines (effective 1 September 2010) provides a procedure for registering and issuing registration certificates for pharmaceutical preparations. Government resolutions adopted pursuant to this law give more detailed procedures for regulating the circulation of medicines.

16 Which authorities may grant marketing authorisation in your jurisdiction?

As of 1 September 2010, medicinal products are registered in Russia by the Department for Regulation of Medicinal Products of the Ministry of Healthcare and Social Development.

17 What are the relevant procedures?

In accordance with the applicable law on the circulation of medicines, state registration must be preceded by the following stages:

- pre-clinical product trials;
- filing of an application for the product's state registration;
- arranging and conducting an expert examination of documentation to obtain a permit for the product's clinical trials;
- arranging and conducting an ethical expert examination;
- clinical trials of the product;
- quality assessment of the product (ie, an expert assessment of proposed quality control methods and quality of product samples using the said methods) and expert risk-benefit assessment for the product;

A decision on the pharmaceutical product's state registration is made on the basis of the results of the above assessments and trials.

State registration of pharmaceutical preparations takes place within 210 days of the registration application being accepted (not including clinical trials and document preparation).

The registration certificate issued for the pharmaceutical product states the presentation and dosage and is issued for an indefinite period, except registration certificates for preparations registered in Russia for the first time, which are issued for a five-year term.

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Applicable law does not provide for state-registered medicinal products to be struck from the state register if they are not marketed within a certain time.

Update and trends

Developing the pharmaceutical industry has been a government priority in recent times. As part of this development, a number of legal initiatives have been passed with a view to modernising and improving the health-care system and, in particular, regulating the circulation of medicinal products and the activities of pharmaceutical companies, and stimulating the development and production of innovative Russian medicinal products. In particular, the most significant measures include the adoption of the following regulatory acts:

The Pharma – 2020 Strategy is the state programme to develop the Russian pharmaceutical sector up to the year 2020. The primary purpose of the Pharma – 2020 Strategy is to revive and increase the domestic and international competitiveness of Russian industry. The Strategy is expected to significantly result in (i) an increase in the share of Russian products on the domestic market to 50 per cent by 2020, (ii) an increase in the share of innovative preparations from local producers to 60 per cent by price, and (iii) an eightfold increase by 2020 in pharmaceutical exports over 2008.

In September 2010, the long-awaited new Federal Law on the Circulation of Medicines entered into force.

On the whole, this law governs the relations involved in the development, expert assessment, state registration, quality control, production, manufacture, storage, transportation, importation, advertising, sale, use and destruction of medicinal products.

Besides setting maximum producer prices for VIM producers, a state register has been established for maximum prices of medicinal preparations on the list, and the organisation and terms of expert assessment, quality and safety requirements for preparations have been amended. The law requires the Russian pharmaceutical industry to switch to good manufacturing practices (GMP) from 1 January 2014.

Effective application of this law will require the adoption of a number of secondary acts, which will provide clear and detailed mechanisms for implementing the law (for example, recognising the results of clinical trials outside Russia, and the procedure for destroying fake, low-quality, and counterfeit medicinal products). A draft law to amend the Administrative Penal Code is also planned, which will eliminate administrative liability loopholes for violations of the law.

It has been reported that the Federal Antimonopoly Service is currently preparing a number of proposals to strengthen state control over pricing and price policy regarding medicines, and to increase regulation of the relationships between pharmaceutical companies and health-care professionals. In particular, these changes will ban pharmaceutical company representatives from making personal visits to medical professionals in the workplace to provide information on products during business hours.

19 Which medicines may be marketed without authorisation?

In accordance with applicable law on the circulation of medicines, state registration is not required for:

- medicinal products prepared by pharmacies, veterinary pharmacies, sole proprietors licensed as pharmacists according to the prescriptions and requirements of medical organisations, or veterinary organisations;
- medicinal plant materials;
- medicinal preparations acquired by individuals outside Russia and intended for personal use;
- preparations intended for export;
- radiopharmaceutical medicinal preparations made by medical organisations in accordance with the law.

20 What, according to the legislation and case law, constitute medicinal products?

Under applicable law on the circulation of medicines, medicinal products are substances or combinations thereof that, upon administration to the human or animal organism, penetrate the organs and tissues, and are used to prevent, diagnose (except substances and combinations not used in contact with the human or animal organism), or treat illness, or to preserve, prevent or terminate pregnancy, and are derived from blood, blood plasma, organs, human or animal tissue, plants or minerals by synthesis or use of biological technologies. Medicinal products include:

- pharmaceutical substances, ie, medicinal products in the form of biological, biotechnological, mineral or chemical substances that are pharmacologically active, used to produce or prepare medicinal preparations and determine their effectiveness; and
- medicinal preparations, ie, medicinal products in medicinal form, used to prevent, diagnose and treat illness, or to preserve, prevent or terminate pregnancy.

Pricing and reimbursement of medicinal products**21 To what extent is the market price of a medicinal product governed by law or regulation?**

Medicinal preparations for medical use, in both outpatient and inpatient sectors, are not generally subject to price regulation.

However, an important exception concerns vitally important medicines (VIM), which are regulated by the following means, in particular:

- approval of certain medicines for inclusion on the VIM List;
- approval of a methodology for setting maximum producer prices for medicinal preparations on the VIM List; and
- state registration of maximum producer prices and the setting of maximum wholesale and retail mark-ups on preparations on the VIM List.

The inclusion of a medicine in the VIM List is formally based on the following criteria:

- use of the medicine for the diagnosis, prevention, or treatment of diseases, including diseases prevalent in Russia;
- advantages of the medicine in comparison with other medicines for a given illness, syndrome, or clinical situation; and
- therapeutic equivalence of the medicine to medicines with a similar pharmacological mechanism of action.

State registration of maximum producer prices is undertaken for:

- medicinal products of Russian producers, in view of the price of similar medicinal products in Russia (using the international generic name, presentation and dosage); and
- medicinal products by foreign producers, on the basis of the minimum price in the country of the producer and other countries where the products have been registered (by international non-proprietary name (INN), presentation and dosage), including comparable transportation costs.

The VIM List is compiled by the Ministry of Health Care and Social Development each year and then approved by the government. The VIM List consists exclusively of medicines that have been duly registered in Russia, and currently includes around 600 medicinal substances.

22 In which circumstances will the national health insurance system reimburse the cost of medicines?

The Russian mandatory medical insurance system provides for limited reimbursement of the cost of medicines as described below.

During inpatient care, free medicines are provided regardless of the duration of treatment, if such medicines are included on the VIM List approved each year. If a patient is prescribed a medicinal product not on the VIM List, the patient must purchase such medicine.

For outpatient care, the reimbursement of the cost of medicines on the VIM List depends on the patient's category and illness. Specifically, prescriptions are filled free of charge for some classes of patients (for example, Second World War veterans, Heroes of Russia and children up to three years of age) and at 50 per cent of retail price for certain other classes (for example, non-working class II disabled, and pensioners receiving a minimum pension). The list of persons qualifying for benefits is established by Federal Law No. 178-FZ dated 17 July 1999 on State Social Care and Government Resolution No. 890 dated 30 July 1994 on State Support for the Development of the Medical Industry and Improvement in the Supply of Medicinal Products and Medical Devices to the Public and Health-care institutions.

Persons not qualifying under the above patient classes are nevertheless entitled to free medicines on the VIM List that are used to treat certain enumerated illnesses (for example, HIV, cerebral palsy, cancer, and tuberculosis).

23 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The government of Russia approves the VIM List.

The Ministry of Health Care and Social Development approves the methodology for pharmaceutical producers to set maximum producer prices for medicinal preparations on the VIM List.

The Federal Tariff Service approves the methodology for regional executive authorities to set maximum wholesale and resale mark-ups on actual producer prices set by producers of medicinal preparations on the VIM List.

24 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

Generally speaking, neither producers nor distributors are obligated to provide a special discount on medicinal products. As noted, of course, if the product is on the VIM List then the price will be fixed; and if the product is being dispensed for outpatient care to one of the classes of persons described in question 22, then a discount is given at the point of retail sale, but is subject to reimbursement by the government.

Medicine quality and access to information

25 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

The production, importation into Russia and sale of fake medicinal products, low-quality medicinal substances, and counterfeit medicinal products is prohibited.

Two of the main licence requirements and conditions for pharmaceutical activities are:

- the licensee's compliance with rules on the production of medicinal products; and
- the licensee's compliance with requirements prohibiting the sale of medicinal products that have lost effectiveness, medicinal products that have expired, fake medicinal products and medicinal products that are unlawful copies of medicinal products registered in Russia. Violation of these requirements is grounds for suspension or cancellation of a pharmaceutical licence (including for wholesale, retail sale and medicinal product preparation).

A draft law has been submitted to the legislature on amendments to the Russian Criminal Code that would establish liability for the production, offer for sale, sale, storage, transportation or importation into Russia of fake medicinal substances.

The importation and distribution of fake and counterfeit medicinal products may also be treated as an intellectual property infringement. In particular, infringement of inventors' and patent rights, unlawful trademark use, and unlawful use of information comprising a commercial secret are subject to criminal penalties ranging up to imprisonment.

26 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

Unlike in EU countries, there are no measures to facilitate the general public's access to information about prescription-only medicines in Russia.

Under the recently adopted law on the circulation of medicines, information on prescription medicinal preparations should be contained only in specialised publications for medical, pharmaceutical, and veterinary professionals.

27 Outline major developments to the regime relating to safety monitoring of medicines.

Applicable law on the circulation of medicines stipulates the procedure for monitoring by the Ministry of Healthcare and Social Development and the Federal Service for Supervision of Health Care and Social Development of the safety of medicines in order to detect potential adverse consequences of use, warn patients, and protect them from use of such preparations. Based on the results of such monitoring, the authorised body may:

- consider suspending use of the medicinal preparation; and
- publish information online concerning decisions to change the instructions for use of a medicinal preparation, or for suspension or reinstatement of the preparation's use.



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